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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|---------------------------------|------------------|
| 09/506,246 | 02/17/2000 | Rex T. Gallagher | 20751002003 | 7248 |
| 21005 | 7590 03/26/2002 | • | | |
| HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 | | | EXAMINER | |
| | | | DELACROIX MUIRHEI, CYBILLE | |
| CONCORD | , MA 01742-9133 | | ART UNIT | PAPER NUMBER |
| | | | 1614 DATE MAILED: 03/26/2002 | 8 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No. Office Action Summary Application No. O9/506,246 Examiner Cybille Delacroix-Muirheid Applicant(s) Applicant(s) GALLAGHER ET AL. | | | | | |
|---|------------------------------|--|--|--|--|
| ' Office Action Summary Examiner Art Unit | | | | | |
| - Camino | | | | | |
| Cybille Delacroix-Muirneid 1614 | | | | | |
| - The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address - | | | | | |
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | |
| | | | | | |
| Responsive to communication(s) filed on <u>January 14, 2002 (C of M Oct. 24, 2001)</u>. This action is FINAL. This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits | e | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | 3 | | | | |
| 4)⊠ Claim(s) <u>1-40</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) <u>1-9,11-18,20-24,26-30,32-38 and 40</u> is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>10,19,25,31 and 39</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | Claim(s) is/are objected to. | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | | | |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 4) Interview Summary (PTO-413) Paper No(s) 5) Notice of Informal Patent Application (PTO-152) 6) Other: . | | | | | |

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DETAILED ACTION

- 1. The claims 10, 19, 25, 31, 39 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Jan. 14, 2002 (Certificate of mailing Oct. 24, 2001).

No claims are cancelled. No new claims are added. Claims 1-40 are currently pending.

Applicant's arguments traversing the previous claims rejection under 35 USC 103(a) set forth in paragraphs 1-3 of the office action mailed April 24, 2001 is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claims rejection under 35 USC 112, paragraph 1, set forth in the office action mailed April 24, 2001 have been considered but are not found to be persuasive.

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Said rejection is maintained essentially for the reasons given previously in the office action mailed April 24, 2001 with the following additional comment:

It is essentially Applicant's position that claims 10, 19, 25, 31 and 39, as amended, are enabled because Applicant has provided evidence that the claimed antibodies are known, reproducible and readily available to the public as evidenced by the Mudgett-Hunter et al. article, <u>J. Immunol.</u>, 129: 1165-1172 (1982).

Said argument has been considered but is not found to be persuasive.

The Examiner respectfully submits that a description of the claimed antibodies in the Mudgett-Hunter et al. article doesn't ensure that the authors will make the antibody readily available to the public. A deposit is still required because it would make the claimed antibody available to the public and would allow one of ordinary skill in the art to practice the claimed invention.

It is for these reasons that the rejection is maintained.

Conclusion

Claims 10, 19, 25, 31, 39 stand rejected.

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

March 21, 2002

PRINTER